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10/826,232	04/16/2004	Carol A. Tosaya	D-03020A	9638

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John w. Sliwa
24871 Olive Tree Lane
Los Altos Hills, CA 94024

EXAMINER

DOUKAS, MARIA E

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,232	Applicant(s) TOSAYA ET AL.	
	Examiner MARIA E. DOUKAS	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 18-23, 26-29, 31-41, 45, 47-50, 53, 57-69 and 71-88 is/are pending in the application.
- 4a) Of the above claim(s) 85-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 18-23, 26-29, 31-41, 45, 47-50, 53, 57-69 and 71-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 4/21/2009 is acknowledged.
2. Claims 85-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/21/2009.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-11, 13, 18-23, 26-27, 31-35, 37-41, 45, 48-50, 53, 57-64, 73, 74, and 76-84 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,713,831 to Olsson (Olsson).

In Reference to Claims 1, 11, 13, 31, 35, 37, 45, 53, 57, 58, 59, 73, 79-80, and 83

Apparatus for the non-contact, non-invasive removal of deposits situated on a natural body part (Figure 3; abstract) having at least one moving or movable part (the thrombus is located in the heart, which has moving parts e.g. valves), the existing deposit

Art Unit: 3767

interfering with a natural circulatory system process (col. 1, lines 6-32, wherein thrombus presence interferes with blood flow), said apparatus comprising: an acoustic emitter (ultrasound transmitter) capable of emitting a beam of acoustic energy (col. 2, lines 14-21); an acoustic matching layer (transmitting units comprising piezoelectric crystals; col. 3, lines 14-15) for non-contact, non-invasive (abstract) acoustic coupling of the acoustic energy beam into said deposits via impingement of the beam upon the deposits (Figure 3; col. 2, lines 22-27; col. 3, lines 14-42) configured to at least partially remove said existing deposits with said beam (abstract); and optionally an administered drug to aid said removal of deposits (col. 1, lines 25-29, wherein thrombolytic drugs are taught as being capable of being used to dissolve the thrombus ; col. 3, line 63-col. 4, line 6).

In Reference to Claims 2-10, 18-19, 39-41, 48-50, 62-64, 74, 76, 81-82, and 84

Claims 2-10, 18-19, 39-41, 48-50, 62-64, 74, 76, 81-82, and 84 are directed towards further specifying the moving part of an implanted device or towards further specifying the deposits. These are described within the preamble of claim 1 in order to provide intended use, and, based on MPEP §2111.02, section II, which states "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Therefore, claims 2-11 are rejected, as they do not add significance to claim 1, which is

Art Unit: 3767

rejected above. Further, the structure of the prior art is capable of being used to remove deposits located on valves within the heart, and since claims 2-11, 18-19, 39-41, 48-50, 62-64, 74, 76, 81-82, and 84 do not go to further limiting the structure of the acoustic apparatus itself, but instead to limiting structure of the external environment that the apparatus is used within, there is therefore no patentable distinction in structure between that claimed and that taught by the prior art - see MPEP §2111.04.

In Reference to Claims 20-22

The device of claim 19 (see above) wherein said emissions result in directly destroying said deposits (abstract, wherein the emission results in the dissolution of the thrombus). Further, the structure of the prior art is capable of being used to direct the emissions towards deposits that are surrounding a valve, and since claims 21-22 do not go to further limiting the structure of the acoustic apparatus itself, but instead to limiting structure of the external environment that the apparatus is used within, there is therefore no patentable distinction in structure between that claimed and that taught by the prior art - see MPEP §2111.04.

In Reference to Claims 23, 26-27

The device of claim 20 (see above) wherein said drug is present and employed before acoustic exposure and accelerates the favorable action of the drug (col. 1, lines 43-45; col. 3, line 63-col. 4, line 6).

Art Unit: 3767

In Reference to Claims 32-34, 77-78

Claims 32-34, 77-78 do not further limit the structure of the apparatus in claim 1, but instead are directed towards the environment that the apparatus is used within. Since the structure taught by the prior art is capable of being used as described in these claims, there is no patentable distinction in structure between that taught by the prior art and that claimed (see MPEP §2111.04).

In Reference to Claim 38

The device of claim 35 (see above) wherein multiple therapy sessions are conducted (this does not further limit the structure of the apparatus in claim 1, but is instead directed towards the environment in which the apparatus is used, and since the structure of the prior art is capable of being used in multiple therapy sessions, there is no patentable distinction in structure between that claimed and that taught by the prior art - see MPEP §2111.04).

In Reference to Claims 60-61

The device of claim 1 (see above) wherein the emitter also comprises an acoustic device used to gather a fingerprint indicative of the extent, location, or nature of the deposits (col. 4, lines 7-13).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 28, 29, 47, 65-69, 71, 72, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,713,831 to Olsson (Olsson).

In Reference to Claims 28-29, 47

Olsson teaches the device of claim 1 (see above) and further teaches that the pulse frequency of the device may be varied within broad limits (col. 3, lines 43-46) and the crystals can emit sound of various wavelengths (col. 2, lines 22-27). Although it is not explicitly taught that the frequency used has a wavelength on the order of the characteristic dimension of the deposits of that purposely excites a resonance, because the structure taught by the prior art is capable of having varying wavelengths emitted and various frequencies used, the structure is capable of having the claimed wavelength matching, and there is therefore no patentable distinction in structure between that claimed and that taught by the prior art (see MPEP §2111.04). Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the wavelength to fall within that claimed, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)).

In Reference to Claims 65-69

Olsson teaches the device of claim 1 (see above) and further teaches wherein the frequency range of the energy is within 10 Hz -10 kHz (col. 3, lines 43-46). This range taught by the prior art falls within the range claimed, and there is therefore no patentable distinction between that claimed and that taught by the prior art (see MPEP §2144.05 for overlap of ranges). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 233).

In Reference to Claims 71-72

Olsson teaches the device of claim 1 (see above) and further teaches wherein the acoustic power ranges from 2 W/cm² to 3 W/cm². This range taught by the prior art falls within the range claimed in claim 71, and there is therefore no patentable distinction between that claimed and that taught by the prior art (see MPEP §2144.05 for overlap of ranges). Further, although the range claimed in claim 72 falls outside that taught by the prior art, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the power range to fall within that claimed, as it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 233).

Art Unit: 3767

In Reference to Claim 75

Olsson teaches the device of claim 74 (see above) and further teaches wherein the frequency range of the energy is within 10 Hz -10 kHz (col. 3, lines 43-46) and the acoustic power ranges from 2 W/cm² to 3 W/cm². Although the ranges claimed fall outside that taught by the prior art, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the power range and frequency range to fall within that claimed, as it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 233).

7. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,713,831 to Olsson (Olsson) in view of U.S. Patent No. 5,725,494 to Briskin (Briskin).

In Reference to Claim 36

Olsson teaches the device of claim 35 (see above) but fails to explicitly teach the type of thrombolytic drug used. Briskin teaches that suitable thrombolytic drugs that can be used include heparin in order to disrupt stenotic material (col. 5, lines 7-17).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Olsson to use heparin as the thrombolytic drug as taught by Briskin in order to disrupt stenotic material (col. 5, lines 7-17). Further, it has been held to be within the general skill of a worker in the art to

Art Unit: 3767

select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (*In re Leshin*, 125 USPQ 416).

Response to Arguments

8. Applicant's arguments with respect to claims 1-11, 13, 18-23, 26-29, 31-41, 45, 47-50, 53, 57-69, and 71-84 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3767

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA E. DOUKAS whose telephone number is (571)270-5901. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MD

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761

Application/Control Number: 10/826,232
Art Unit: 3767

Page 11